

U.S.S.N. 09/933,548  
Art Unit: 1634  
Filed: August 20, 2001  
AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

### In the claims

1. (original) A method of determining the susceptibility of a human patient to prostate cancer comprising the steps of (i) obtaining a sample containing nucleic acid and/or protein from prostate cells of the patient; and (ii) determining whether the sample contains a level of Pax 2 nucleic acid or protein associated with prostate cancer.
2. (original) A method of diagnosing prostate cancer in a human patient comprising the steps of (i) obtaining a sample containing nucleic acid and/or protein from prostate cells of the patient; and (ii) determining whether the sample contains a level of Pax 2 nucleic acid or protein associated with prostate cancer.
3. (original) A method of predicting the relative prospects of a particular outcome of prostate cancer in a human patient comprising the steps of (i) obtaining a sample containing nucleic acid and/or protein from prostate cells of the patient; and (ii) determining whether the sample contains a level of Pax 2 nucleic acid or protein associated with prostate cancer.
4. (currently amended) A method according to any ~~one of claims 1 to 3~~ of claims 1, 2 or 3 wherein the cancer is invasive.
5. (currently amended) A method according to any ~~one of the preceding claims~~ of claims 1, 2 or 3 wherein the sample contains nucleic acid and the level of Pax 2 nucleic acid is measured by contacting the nucleic acid with a nucleic acid which hybridises selectively to Pax 2 nucleic acid.
6. (original) A method according to claim 5 wherein the sample contains mRNA and the nucleic acid selectively hybridises to Pax 2 mRNA.

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7. (currently amended) A method according to claim 5 ~~or 6~~ wherein the nucleic acid which hybridises is detectably labelled.

8. (currently amended) A method according to ~~any one of claims 5 to 7~~ claim 5 wherein the nucleic acid which selectively hybridises is detectably labelled.

9. (currently amended) A method according to ~~any one of claims 5 to 8~~ claim 5 wherein the nucleic acid which selectively hybridises is suitable for use in a nucleic acid amplification reaction.

10. (currently amended) A method according to ~~any one of claims 1 to 4~~ of claims 1, 2 or 3 wherein the sample contains protein and the level of Pax 2 protein is measured.

11. (original) A method according to claim 10 wherein the level of protein is measured by contacting the protein with a molecule which selectively binds to Pax 2 protein.

12. (original) A method according to claim 11 wherein the selective binding molecule is an antibody or fragment or derivative thereof or an antibody-like molecule.

13. (original) A method according to claim 11 or 12 wherein the selective binding molecule comprises a detectable label.

14. (original) A method according to claim 10 wherein the level of Pax 2 is measured by selectively assaying its activity in the sample.

15. (currently amended) A method according to ~~any one of claims 1 to 14~~ of claims 1, 2 or 3 wherein the sample is a sample of the tissue in which prostate cancer is suspected or in which prostate cancer may be or has been found, or contains cells from said tissue.

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16. (original) A method according to claim 15 wherein the sample is any one of urine, semen, blood or lymphatic circulation.

17. (currently amended) ~~Use of~~ A method of diagnosing prostate cancer comprising administering an agent which is capable of use in determining the level of Pax 2 protein or nucleic acid in a sample in the manufacture of a reagent for diagnosing prostate cancer.

18. (currently amended) ~~Use according to~~ The method of claim 17 wherein the agent is a nucleic acid which selectively hybridises to Pax 2 nucleic acid.

19. (currently amended) ~~Use according to~~ The method of claim 18 wherein the agent is a molecule which selectively binds to Pax 2 protein.

20. (currently amended) ~~Use according to~~ The method of claim 19 wherein the agent is useful in selectively assaying the activity of Pax 2 protein.

21. (cancel)

22. (cancel)

23. (currently amended) A kit ~~of parts useful~~ for diagnosing prostate cancer comprising an agent which is capable of use in determining the level of Pax 2 protein or nucleic acid in a sample and a control sample wherein the control sample may be a negative control not comprising a detectable amount of Pax 2 nucleic acid or protein, or it may be a positive control comprising a detectable amount of Pax 2 nucleic acid or protein.

24. (original) A method of treating prostate cancer comprising the step of administering to the patient an agent which selectively prevents the function of Pax 2.

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25. (original) A method according to claim 24 wherein the agent prevents the expression of Pax 2.

26. (original) A method according to claim 24 wherein the agent inhibits the activity of Pax 2.

27. (original) A method according to claim 26 wherein the agent is an antisense molecule.

28. (original) A method according to claim 26 wherein the agent is a ribozyme.

29. (currently amended) ~~Use of A method of treating prostate cancer comprising administering an agent which selectively prevents the function of Pax 2 in the manufacture of a medicament for treating prostate cancer.~~

30. (original) A genetic construct a nucleic acid encoding a molecule capable of preventing the function of Pax 2 expressed in a prostate cell.

31. (original) A genetic construct according to claim 30 adapted for delivery to a human prostate cell.

32. (original) A genetic construct according to claim 31 wherein the adaptation allows delivery to a prostate cancer cell.

33. (currently amended) A genetic construct according to claim 31 ~~or 32~~ comprising means to selectively deliver the nucleic acid to a prostate cancer cell.

34. (currently amended) A genetic construct according to ~~any one of claims 30 to 33~~ claim 30 comprising means to selectively express the nucleic acid encoding a molecule in a prostate cancer cell.

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35. (cancel)

36. (currently amended) A pharmaceutical composition comprising a genetic construct according to any one of claims 30 to 34 comprising a nucleic acid encoding a molecule capable of preventing the function of Pax 2 expressed in a prostate cell and a pharmaceutically acceptable carrier.

37. (currently amended) Any novel method of diagnosing prostate cancer substantially as described herein, preferably with reference to one or more of the examples The method of claim 2 wherein the step of determining whether the sample contains a level of Pax 2 protein associated with prostate cancer is carried out using western blotting.

38. (cancel)